

**Results:** A total of 2262 patients (62.1 [20.2] years (range, 17–102), 1172 female) were evaluated in the study. Of these, 426 (18.8%) took psychotropic drugs at home. Comparing patients taking psychotropic drugs with patients not taking these drugs, they were significantly older (72.7 vs 59.7 years), took significantly more drugs at home (8.1 vs 3.6), and stayed significantly longer at the hospital (7.4 vs 5.3 days) (all,  $P < 0.0001$ ). In 134 (31.5%) patients taking psychotropic drugs, we identified 162 ADE (106 adverse drug reactions including QTc-prolongation, 56 associated with at least 1 medication error) as well as 98 medication errors without or with unknown clinical consequences. In 80 patients, 1 or more ADE related to psychotropic drugs was a major contributing factor to hospitalization. Most frequently, patients suffered from the following symptoms: syncope ( $n = 33$ ), somnolence ( $n = 12$ ), seizures ( $n = 10$ ), and anticholinergic effects ( $n = 8$ ). In 49 (59.8%) of the 82 ADE associated with hospitalization, a drug–drug interaction was involved. At least 1 medication error (eg, ignored contraindication or missing indication) was involved in 31 (37.8%) of the ADE associated with hospitalization, which were, therefore, judged to be preventable. Based on the data available for 72 (87.8%) of the patients hospitalized because of ADE, the average treatment costs of ADE-related to psychotropic drugs was €2556 (2148).

**Conclusion:** Nearly one third of all patients taking psychotropic drugs suffered from a psychotropic drug-related ADE and nearly one fifth were hospitalized in relation to the ADE. That is, ADE due to psychotropic drugs are common, costly, and often preventable. Strategies have to be found to ensure the safe use of psychotropic drugs, especially for the elderly people with polypharmacy.

**Disclosure of Interest:** None declared.

#### PP025—IMPROVING HY'S LAW DEFINITION TO BETTER PREDICT THE RISK OF DEVELOPING ACUTE LIVER FAILURE IN DRUG-INDUCED LIVER INJURY (DILI)

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**Introduction:** Prediction of serious DILI at early stages of drug development is a major concern. A broad “Hy’s Law” definition as  $ALT > 3 \times ULN$  and total bilirubin (TBL)  $> 2 \times ULN$  has been used to predict a worst DILI outcome. We aimed to examine the best way to define Hy’s law by analyzing whether the R value provides a better way of identifying hepatocellular (HC) versus cholestatic (Chol) contribution to injury at different time points, and whether an alkaline phosphatase (ALP) value above 2-fold indicates Chol predominance and low risk of acute liver failure/liver transplantation (ALF/OLT).

**Patients (or Materials) and Methods:** The study cohort encompasses all patients with idiosyncratic DILI submitted to the Spanish DILI Registry until 2012. Clinical and biochemical analyses were performed using available information from 805 episodes in 771 patients at 3 different time points: DILI onset, peak of ALT, and peak of TBL. **Results:** Thirty-one (4%) patients developed ALF/OLT. Sixty-five percent of the cases were HC ( $nR \geq 5$ ;  $nR$  calculated with AST or ALT (which ever being the highest)  $\times ULN/ALP \times ULN$ ). Of these, 28 cases (5.5%) had ALF/OLT whereas only 2 (0.7%) in the chol/mixed group. Risk factors significantly associated to DILI-induced ALF/OLT were HC injury, female sex, high AST/ALT ratio, and TBL. To ascertain the best criteria for predicting ALT/OLT cases, we compared

all cases that fulfilled “Hy’s Law” definition according to  $ALT > 3 \times ULN$ ,  $R \geq 5$  ( $ALT \times ULN/ALP \times ULN$ ) or  $nR \geq 5$  and  $TBL > 2 \times ULN$  at various time points.  $nR$  criteria showed a better balance between sensitivity and specificity, mainly at onset as type of injury evolves into Chol damage. Of 282 who fulfilled these criteria, 27 had ALF/OLT at onset, 25 of 280 at ALT peak, and 18 of 266 at TBL peak. The sensitivity ranged from 72% to 90% and specificity ranged from 62% to 65%. Incidences of  $ALP \geq 2 \times ULN$  in patients who did or did not go on to develop ALF/OLT were similar and rarely  $\geq 4 \times ULN$ . **Conclusion:** DILI patients with HC injury ( $nR \geq 5$ ) show a higher risk of ALF/OLT than Chol/Mix damage, with highest predictive value at DILI onset. Risk factors for ALF/OLT are HC injury, female sex, high AST/ALT ratio, and TBL. The definition of Hy’s law with  $nR$  at the first blood test available after presentation shows the major predictive value. Therefore, delayed presentation can complicate assessment of ALF risk. ALP levels  $> 2 \times ULN$  do not exclude “true” Hy’s law cases and do not predict a lower risk of ALF/OLT.

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#### PP026—MEDIGENIA: INNOVATIVE CLOUD BASED SOLUTION FOR PHARMACOVIGILANCE

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**Introduction:** Adverse drug reactions (ADR) are the fourth cause of death in Western Countries: people receive multiple medications, and resulting drug response may differ significantly from expected outcomes. Medigenia is a free health service that prevents ADR using the social security number (SSN).

**Patients (or Materials) and Methods:** Medigenia is a cloud-based smart city that collects patient’s drug recruitment information from all the sources of exposure (pharmacy, general physician (GP), hospital). The patient, freely registered to the service, is related through her/his SSN with the list of drugs administered. The element that connects all health actors is a software solution that permits the creation of a unique electronic space where patient profiles are stored and updated. Medigenia supports GP in his decisions, providing him with an online pharmacologic profile of the patients, information about prescribed drugs/over the counter (OTC)/herbs, detailing dosage, number of packages and pills per package, prescription/purchase date, drug half-life, drug–drug interactions (DDIs), therapeutic index, and prescribing doctor. System also provides important information about patient’s global health status, inspecting comorbidity (Charlson age-adjusted Comorbidity Index), allergy, organ failure, and glucose 6 phosphate dehydrogenase deficit. Every complete profile permits to define, for each patient, a priori risk, expressed in percentage, which represents the probability of heading for ADR after taking a new drug. Range percentage identifies the risk among 3 cutoffs: low (from 25% to 50%), moderate (from 50.1% to 75%) and high ( $> 75.1\%$ ). Medigenia integrates a real-time alerting system that is automatically activated when pharmacologic risk, strictly related to a priori risk of the patient, overcomes those cutoffs: overtaken them, the doctor received a warning by e-mail for a timely therapy update.